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10/553,760	08/21/2006	Anniina Honkanen	019075-00072	5960
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ARENT FOX LLP			WILLIAMS, LELA	
1050 CONNECTICUT AVENUE, N.W.				
SUITE 400			ART UNIT	PAPER NUMBER
WASHINGTON, DC 20036			1794	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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IPMatters@arentfox.com
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Office Action Summary	Application No.	Applicant(s)	
	10/553,760	HONKANEN ET AL.	
	Examiner	Art Unit	
	LELA S. WILLIAMS	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-34 is/are pending in the application.
 - 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-34 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. ____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>10/20/2005, 12/15/2005</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: ____ .

DETAILED ACTION

Claim Objections

1. Claims 3-9 are objected to because of the following informalities: The claims recite “The product according to”, please change to “the product of”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites “for replacing part of the taste masking sweetening agent”. It is unclear to how much is "part of".

Claims 2 and 33 recites “wherein the amount of sweetening agent is reduced as compared to a regular product”. It is unclear as to what is considered a regular product.

Claims 3, 5, 6, and 9-31 recites the broad amount range of plant sterol and/or sweetening agents, viscosity or citrus fruit juice, and the claims also recites a “preferably/more preferably/most preferably” range which is the narrower statement of the range/limitation. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by

"such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

Claims 15-18, 27, and 28 recite soy based drinks/products. It is unclear to what this is. Is this the same as soy milk based drink? How does this differ from the soy milk based drinks?

Regarding claims 24 and 25, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claims 26-29, the phrase "like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claim 32 recite "a sweetening agent in an amount less than the one present in a regular product" (line 3). The amount is unclear and as is what regular product is this presently being compared to?

Claim 34 provides for the use of a plant sterol ester, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 34 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 7, 8, 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Sarama et al. WO 01/54686.

Regarding claims 1, 7, 8, 32, and 34; Sarama teaches an edible product comprising a sweetening agent (page 27, third paragraph) and a plant sterol/stanol ester (page 7, third paragraph). The sweetening agent will inherently characteristically mask a bitter, sour and/or astringent taste. The plant sterol/stanol esters component of the reference is present in an amount of 0.0001% to 25% (page 8, third paragraph). Sarama states that a combination of sterols/stanols is able to disguise adverse flavors (page 8, first paragraph) but does not disclose the use of the ester for replacing part of the sweetening agent. However, the recitation in the claims that the plant sterol ester is “for replacing part of the taste masking sweetening agent” is merely an intended use. Applicants attention is drawn to MPEP 2111.02 which states that intended use statements must be evaluated to determine whether the intended use results in a structural

difference between the claimed invention and the prior art. Only if such structural difference exists, does the recitation serve to limit the claim. If the prior art structure is capable of performing the intended use, then it meets the claim.

It is the examiner's position that the intended use recited in the present claims does not result in a structural difference between the presently claimed invention and the prior art and further that the prior art structure is capable of performing the intended use. Given that Sarama disclose a plant sterol ester as presently claimed in amount as presently claimed, it is clear that the plant sterol ester of Sarama would be capable of performing the intended use, i.e. replacing part of the taste masking sweetening agent, presently claimed as required in the above cited portion of the MPEP.

Regarding claims 2 and 33, Sarama discloses an edible product in the form of dietary foods to meet the needs of persons who are obese or diabetic (page 36, third paragraph) comprising a sweetening agent and 0.0001% to 25% of plant sterol/stanol esters (page 8, third paragraph). It is inherent that these foods would have an amount of sweetening agent present in them which is considered reduced as compared to a regular product.

Regarding claim 3, Sarama discloses the plant sterol ester present in an amount of 0.0001% to 25%, thus encompassing present range (page 8, third paragraph).

Regarding claims 4, Sarama discloses a product as applied to claim 1 wherein the sweetening agent comprises carbohydrates and non-carbohydrates (page 28).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1794

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 5, 6, 9, 11-12, 20-23, and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarama et al. WO 01/54686.

Regarding claim 5, Sarama discloses a product as applied to claim 4, wherein carbohydrate or non-carbohydrate sweetener agents are added to the product in the amount of 0.1% to 20% (page 28, line 1). The reference does not give the specific amount of each agent used, but does state the amount of sweetener will depend on the particular sweetener used and

the sweetness intensity desired (page 27, third paragraph). Given this information, the determination of the amount of sweetener would be considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed amount cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the amount of each sweetener needed to obtain the desired product (In re Boesch, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (In re Aller, 105 USPQ 223).

Regarding claim 6, Sarama discloses a product as applied to claim 1, but the reference does not disclose the reduced range amount. However, regardless of how the reference achieved the amount, it is significant to note the reference discloses the amount of sweetening agent in the composition is from 0.1% to 20%, which would encompass that of the present invention.

Regarding claim 9, Sarama discloses a product as applied to claim 1, to be a beverage, such as teas, colas, fruit juice, or near-water (page 21, fourth paragraph). The reference does not teach the viscosity of said beverages; however they are known to be of low viscosity. Knowing that these drinks are usually “thin” and greatly accepted by the consumer as being so, it would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the beverages to have a low viscosity in the Pascal range including as presently claimed, in order to produce a beverage with the known desired thinness/thickness of the final beverage.

Regarding claims 11, 12, 20-23, 29, 30, and 31, Sarama discloses a beverage and food, i.e. ice cream (page 21, third paragraph), which comprises plant sterol ester and a carbohydrate

or non-carbohydrate sweetening agent. Sarama discloses that the plant sterol ester compound is particularly useful in such beverages as those containing 0.1% to 40% fruit juices or fruit flavors (berries and citrus are explicitly listed in paragraph 2, page 25) milks, coffees, teas, and fortified drinks e.g. a liquid meal replacement (page 21, 3rd para.-page 22, 1st para.). The reference also teaches adding flavors such as chocolate (page 26, second paragraph). The disclosure of a “milk based [flavor] drink” is not explicitly stated, however given the disclosure of the drinks/flavors, it would have been obvious to one of ordinary skill to combine milk with chocolate to yield a milk based cocoa drink or milk with coffee thus yielding a milk based coffee drink. The mixtures of milk/cocoa and milk/coffee are beverages that have long been established and accepted. The specific amounts of plant sterol and carbohydrate or no-carbohydrate sweetening agents used in the drinks are not disclosed and the amount of citrus fruit juice falls slightly outside of the claimed range of at least 50%, but since the general ranges of 0.0001% to 25% of plant sterol/stanol esters and 0.1% to 20% of carbohydrate or no-carbohydrate sweetening are given, it would have been within the skill level of one of ordinary skill in the art to develop a beverage, including the presently claimed beverage, with a suitable amount of additives, including citrus fruit juice, to achieve the desired taste of the final product. One of ordinary skill would have optimized, by routine experimentation, a desired amount of plant sterol, sweetener, either carbohydrate or non-carbohydrate, and fruit juice (In re Boesch, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)). Since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (In re Aller, 105 USPQ 223). As such, without showing unexpected results, the claimed amount cannot be considered critical.

10. Claims 10, 13-18, and 26-28 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Sarama et al. WO 01/54686 in view of Yoon et al. WO 02/28204.

Regarding claims 10, 13-18, and 26-28; Sarama discloses adding plant sterol ester in an amount of 0.0001% to 25% and a carbohydrate or non-carbohydrate sweetening agent in an amount of 0.1% to 20% to a milk beverage (page 21, 3rd para.-page 22, 1st para.) and other dairy products such as ice cream, milkshakes, and milk products (page 21, 3rd para.), which would all be a “yoghurt-like product”; however the references disclosure of a milk beverage/products and additive amounts are general and it does not specifically list a cereal milk based drink/product, soy based yoghurt-like product, or the specific amounts of sweetener agent. Yoon teaches adding plant sterol to various beverages (page 1, line 5) including water, juices, coffee, tea, milk, soy milk, and those made of grain (page 9, line 30), which are also considered cereals. Given that the reference teaches the use of soy milk, as well as juices and coffee, it would have been obvious to one of ordinary skill in the art to combine soy with the other milk beverages/ products to enhance the nutritional value of fruit juice, coffee drinks and “yoghurt-like” products. Since the instant specification is silent to unexpected results, the specific amounts of plant sterol ester and carbohydrate or non-carbohydrate sweetener agent amount are not considered to confer patentability to the claims. As the flavor is a variable that can be modified, among others, by adjusting the amount of sweetener, the precise amount would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed amount cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have

optimized, by routine experimentation, the amount of plant sterol ester and sweetener agent in Sarama to obtain the desired flavor (In re Boesch, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (In re Aller, 105 USPQ 223). One of ordinary skill in the art would have been motivated to combine the teaching of Sarama with those of Yoon in order to produce a product which has not only good taste but also added health benefits.

11. Claims 19, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarama et al. WO 01/54686 in view of Vulpson et al. WO 00/41491.

Sarama discloses adding plant sterol ester in an amount of 0.0001% to 25% and a sweetener agent in an amount of 0.1% to 20 to a milk beverage; however the references disclosure of a milk beverage and additive amounts are general and it does not specifically list a fermented milk based drink or the type of sweetener agent. Vulpson teaches adding plant sterols to fermented milk products such as yoghurt (page 1, line 12). The reference discloses a product based on whey protein and plant sterols (page 23, line 20). Since the instant specification is silent to unexpected results, the specific amounts of plant sterol ester and sweetener agent and also the use of a carbohydrate verses non-carbohydrate sweeteners, is not considered to confer patentability to the claims. As the flavor is a variable that can be modified, among others, by adjusting the amount of the additives or the type of sweetener, the precise amount would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed amount cannot

be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the amount of plant sterol ester and sweetener agent in Sarama to obtain the desired flavor (In re Boesch, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)). Since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (In re Aller, 105 USPQ 223). One of ordinary skill in the art would have been motivated to combine the teaching of Sarama with those of Vulpson in order to produce a food/drink product which has not only good taste but also added health benefits.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. WO 02/082929 and JP 2003-819979 are cumulative to the rejections of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LELA S. WILLIAMS whose telephone number is (571)270-1126. The examiner can normally be reached on Monday to Thursday from 7:30am-5pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on 571-272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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